UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,457	11/02/2000	James Andya	P0998D3	7899

9157 7590 07/20/2005

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
DIBRINO, MARIANNE NMN	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 07/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/705,457	11/02/2000	James Andya	P0998D3	7899

9157 7590 08/02/2004

GENENTECH, INC.
1 DNA WAY
SOUTH SAN FRANCISCO, CA 94080

EXAMINER	
DIBRINO, MARIANNE NMN	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 08/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/705,457	ANDYA ET AL.	
	Examiner	Art Unit	
	DiBrino Marianne	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37,44-46 and 49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37, 44-46 and 49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 4/21/04 is acknowledged and has been entered.

Claims 37-39 and 44-49 are pending and are presently being examined.

The following are new grounds of rejection necessitated by Applicant's amendment filed 4/21/04.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 37, 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Davis et al (Springer Semin. Immunopathol 1993, 15: 51-73) in view of U.S. Patent No. 5,783,186, US Patent No. 5,965,709, U.S. Patent No. 4,093,606 and Cleland et al (Proceed. Intern. Symp. Control. Rel. Bioact. Mater, 22 (1995), pages 514-515).

Davis et al teach administration of an anti-IgE antibody, i.e., a protein, to humans to treat allergic diseases, said administration resulting in achievement of an initial plasma concentration of from 1ug/ml, to effect binding to circulating IgE and an initial plasma concentration of 10-100 ug/ml to effect binding to IgE-producing B cells. Davis et al teach that a 30-mg intravenous dose of the anti-IgE antibody CGP 51901 would be the estimated amount of antibody to achieve the former initial plasma concentration and by extension, a minimum of a 300 mg dose would achieve the latter initial plasma concentration.

Davis et al do not teach the concentration of the anti-IgE antibody, nor subcutaneous injection.

U.S. Patent No. 5,783,186 discloses administration of monoclonal antibodies to humans may be subcutaneous, intravenous or intramuscular and may be a single bolus injection. U.S. Patent No. 5,783,186 further teaches that the amount of antibody to be used will vary depending upon the nature and severity of the condition but in general will range from about 0.1 ug/kg body weight to about 100 mg/kg body weight, i.e., about 70 mg in a normal size adult, more in a heavier adult.

U.S. Patent No. 5,965,709 discloses allergy therapy (i.e., IgE-mediated disease) by administration of an anti-IgE antibody or anti-IgE fragments such as Fab or Fab' (especially col. 32, para 3), including by subcutaneous injection (especially col. 33, para 1) in amounts of about 2-3 mg/kg, i.e., 140 mg to 210 mg in an average adult and including in a single bolus (especially column 33, para 4). U.S. Patent No. 5,965,709 further discloses pharmaceutical excipients which would serve as lyoprotectants such as mannitol, lactose, starch, magnesium carbonate, magnesium stearate, sodium saccharin and cellulose (especially col. 33, para 1). U.S. Patent No. 5,965,709 discloses subcutaneous or iv administration (especially column 33 at lines 12-14).

U.S. Patent No. 4,093,606 discloses a reconstituted (from lyophilized form) formulation of antibody for use in treating infection in a mammal, including humans, comprising glycine, albumin and a non-ionic surfactant, the said antibody in the amount of 50 mg/ml (i.e.,5%) (especially column 3 at lines 20-23, column 1 at lines 21-32, column 5 at line 50 through column 6 at line 36).

Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and protein concentrations of 134 mg/ml or 400 mg/ml.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the anti-IgE antibody taught by Davis et al or by US Patent No. 5,965,709 in a single bolus as taught by U.S. Patent No. 5,783,186 or U.S. Patent No. 5,965,709 in the amounts taught by Davis et al, US Patent No. 5,783,186 or U.S. Patent No. 5,965,709 at the concentrations such as those taught by U.S. Patent No. 4,093,606 or Cleland et al, i.e., ranging from 50 mg/ml to around 100 mg/ml or higher for administration to humans, as taught by U.S. Patent No. 4,093,606 or Cleland et al. It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have used a higher concentration of antibody than that taught by U.S. Patent No. 4,093,606, i.e., higher than 50 mg/ml because U.S. Patent No. 5,965,709 discloses 140 mg-210 mg amounts for administration to humans (including in a single bolus), Davis et al teach administration of 30 mg-300 mg doses for administration to humans and U. S. Patent No. 5,783, 186 discloses administration of 70 mg in a single bolus injection, including via subcutaneous route, in a normal size adult.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat allergic diseases as taught by Davis et al or by U.S. Patent No. 5,965,709 by routes of administration taught by Davis et al or disclosed by U.S. Patent No. 5,783,186, in the total amounts taught by Davis et al or U.S. Patent No. 4,093,606 or by U.S. Patent No. 5,965,709 in a single bolus as taught by U.S. Patent No. 5,783,186 and at the amounts taught by U.S. Patent No. 4,093,606 or Cleland et al. One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat allergic diseases in a human and including in a heavier than normal size adult.

Applicant's arguments in the amendment filed 4/21/04 have been fully considered but are not persuasive.
Applicant's arguments are of record in the said amendment.

It is the Examiner's position with regard to Applicant's arguments as to Arkawa et al (US Patent No. 5,783, 186) that US Patent No. 5,783, 186 discloses use of an IgG antibody as does Davis et al and as does U.S. Patent No. 5,965,709, although the specificity of each antibody is different. It is the Examiner's further position that Davis et al teach the estimated dosage range to achieve the initial plasma concentration of the antibody for treatment of allergic disease and that US Patent No. 5,783, 186 is relied upon to teach the concentration range of administration of antibodies to humans whether iv, sc or im that may be administered in a single bolus injection is about 70 mg in a normal size adult or more in a heavier adult. It is the Examiner's position that US Patent No. 4,093,606 is relied upon for disclosure of a reconstituted (from lyophilized form) formulation of antibody for use in treating a human comprising glycine, albumin and a non-ionic surfactant, the said antibody at high concentration at 50 mg/ml, and that Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and that the antibodies taught by the other references are proteins.

4. Claims 37, 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Froehlich et al (J. Allergy Clin Immunology, Jan. 1995, IDS reference) in view of U.S. Patent No. 5,783,186, U.S. Patent No. 5,965,709, U.S. Patent No. 4,093,606 and Cleland et al (Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22 (1995), pages 514-515).

Froehlich et al teach administration of anti-IgE antibody to patients with IgE-mediated allergic disease, subcutaneously or intravenously.

Froehlich et al do not teach the concentration of antibody recited in the instant claims.

U.S. Patent No. 5,783,186 discloses administration of monoclonal antibodies to humans may be subcutaneous, intravenous or intramuscular and may be a single bolus injection. U.S. Patent No. 5,783,186 further teaches that the amount of antibody to be used will vary depending upon the nature and severity of the condition but in general will range from about 0.1 ug/kg body weight to about 100 mg/kg body weight, i.e., about 70 mg in a normal size adult, more in a heavier adult.

U.S. Patent No. 5,965,709 discloses allergy therapy (i.e., IgE-mediated disease) by administration of an anti-IgE antibody or anti-IgE fragments such as Fab or Fab' (especially col. 32, para 3), including by subcutaneous injection (especially col. 33, para 1) in amounts of about 2-3 mg/kg, i.e., 140 mg to 210 mg in an average adult and including in a single bolus injection (especially column 33, para 4). U.S. Patent No. 5,965,709 further discloses pharmaceutical excipients which would serve as lyoprotectants such as mannitol, lactose,

starch, magnesium carbonate, magnesium stearate, sodium saccharin and cellulose (especially col. 33, para 1). U.S. Patent No. 5,965,709 discloses subcutaneous or iv administration (especially column 33 at lines 12-14).

U.S. Patent No. 4,093,606 discloses a reconstituted (from lyophilized form) formulation of antibody for use in treating infection in a mammal, including humans, comprising glycine, albumin and a non-ionic surfactant, the said antibody in the amount of 50 mg/ml (i.e.,5%) (especially column 3 at lines 20-23, column 1 at lines 21-32, column 5 at line 50 through column 6 at line 36).

Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and protein concentrations of 134 mg/ml or 400 mg/ml.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the anti-IgE antibody taught by Froehlich et al or disclosed by U.S. Patent No. 5,965,709 in a single bolus as disclosed by U. S. Patent No. 5,783,186 in the amounts disclosed by U.S. Patent No. 4,093,606 or U.S. Patent No. 5,965,709 to humans at the concentration taught by U.S. Patent No. 4,093,606 or higher for a larger adult, or at a higher concentration such as 134 mg/ml taught by Cleland et al.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat allergic diseases as taught by Froehlich et al or as disclosed by U.S. Patent No. 5,965,709, by routes of administration taught by Froehlich et al or disclosed by U.S. Patent No. 5,783,186 or U.S. Patent No. 5,965,709, in the total amounts taught by U.S. patent No. 5,783,186 and U.S. Patent No. 5,965,709 in a single bolus as taught by U.S. Patent No. 5,783,186 at the concentration taught by U.S. Patent No. 4,093,606 or higher concentrations achievable as taught by Cleland et al in order to treat larger size adults or to achieve single bolus injection as disclosed by U. S. Patent No. 5,783,186 or U.S. Patent No. 5,965,709 in the amounts disclosed by U.S. Patent No. 4,093,606 or U.S. Patent No. 5,965,709.

Applicant's arguments in the amendment filed 4/21/04 have been fully considered but are not persuasive.

Applicant's arguments are of record in the said amendment.

It is the Examiner's position with regard to Applicant's arguments as to Froehlich et al (US Patent No. 5,783, 186, that US Patent No. 5,783, 186 discloses use of an IgG antibody as does U.S. Patent 5,965, 709. It is the Examiner's further position that U.S. patent No. 5,783,186 and U.S. Patent No. 5,965,709 disclose the estimated dosage range to achieve the initial plasma concentration of the antibody for treatment of allergic disease and that US Patent No. 5,783, 186 is relied upon to teach the concentration range of administration of antibodies to

humans whether iv, sc or im that may be administered in a single bolus injection is about 70 mg in a normal size adult or more in a heavier adult. It is the Examiner's position that U.S. Patent No. 4,093,606 is relied upon for disclosure of a reconstituted (from lyophilized form) formulation of antibody for use in treating a human comprising glycine, albumin and a non-ionic surfactant, the said antibody at high concentration at 50 mg/ml, and that Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and that the antibodies taught by the other references are proteins.

5. Claims 37, 44-46 and 49 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,543,144 in view of U.S. Patent No. 5,783,186, U.S. Patent No. 5,965,709, U.S. Patent No. 4,093,606 and Cleland et al (Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22 (1995), pages 514-515).

U.S. Patent No. 5,543,144 discloses treatment of patients afflicted with IgE-mediated allergy in amounts sufficient to eliminate substantially IgE-producing cells and to deplete IgE, i.e., 30-500 mg/dose/subject in humans. U.S. Patent No. 5,543,144 further discloses subcutaneous or intravenous injection of anti-IgE antibody.

U.S. Patent No. 5,543,144 does not disclose the specific concentration of the 30-500 mg dose of antibody.

U.S. Patent No. 5,783,186 discloses administration of monoclonal antibodies to humans may be subcutaneous, intravenous or intramuscular and may be a single bolus injection. U.S. Patent No. 5,783,186 further teaches that the amount of antibody to be used will vary depending upon the nature and severity of the condition but in general will range from about 0.1 ug/kg body weight to about 100 mg/kg body weight, i.e., about 70 mg in a normal size adult, more in a heavier adult.

U.S. Patent No. 5,965,709 discloses allergy therapy (i.e., IgE-mediated disease) by administration of an anti-IgE antibody or anti-IgE fragments such as Fab or Fab' (especially col. 32, para 3), including by subcutaneous injection (especially col. 33, para 1) in amounts of about 2-3 mg/kg, i.e., 140 mg to 210 mg in an average adult including in a single bolus injection (especially column 33, para 4). U.S. Patent No. 5,965,709 further discloses pharmaceutical excipients which would serve as lyoprotectants such as mannitol, lactose, starch, magnesium carbonate, magnesium stearate, sodium saccharin and cellulose (especially col. 33, para 1). U.S. Patent No. 5,965,709 discloses subcutaneous or iv administration (especially column 33 at lines 12-14).

U.S. Patent No. 4,093,606 discloses a reconstituted (from lyophilized form) formulation of antibody for use in treating infection in a mammal, including humans, comprising glycine, albumin and a non-ionic surfactant, the said antibody in the amount of 50 mg/ml (i.e.,5%) (especially column 3 at lines 20-23, column 1 at lines 21-32, column 5 at line 50 through column 6 at line 36).

Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and protein concentrations of 134 mg/ml or 400 mg/ml.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the anti-IgE antibody disclosed by U.S. Patent No. 5,543,144 or by U.S. Patent No. 5,965,709 in a single bolus as disclosed by U.S. Patent No. 5,783,186 or by U.S. Patent No. 5,965,709 in the total amounts disclosed by U.S. Patent No. 5,783,186 or by U.S. Patent No. 5,965,709 for administration of monoclonal antibodies to humans in the concentration taught by U.S. Patent No. 4,093,606 or higher as taught by Cleland et al for proteins.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat allergic diseases as disclosed by U.S. Patent No. 5,543,144 or by U.S. Patent No. 5,965,709, by routes of administration disclosed by U.S. Patent No. 5,543,144 or by U.S. Patent No. 5,783,186 or by U.S. Patent No. 5,965,709, in the total amounts disclosed by U.S. Patent No. 5,543,144 or by U.S. Patent No. 5,965,709 in a single bolus as taught by U.S. Patent No. 5,783,186 or by U.S. Patent No. 5,965,709 at the concentration disclosed U.S. Patent No. 4,093,606 or higher as taught by Cleland et al for proteins in order to treat larger size adults or to achieve single bolus injection as disclosed by U. S. Patent No. 5,783,186 in the amounts disclosed by U.S. Patent No. 4,093,606 or U.S. Patent No. 5,965,709.

Applicant's arguments in the amendment filed 4/21/04 have been fully considered but are not persuasive.

Applicant's arguments are of record in the said amendment.

It is the Examiner's position with regard to Applicant's arguments as to U.S. Patent No. 5,543,144, that U.S. Patent No. 5,543,144 discloses use of an IgG antibody as does U.S. Patent No. 5,783, 186 and U.S. Patent 5,965, 709. It is the Examiner's further position that U.S. patent No. 5,783,186 and U.S. Patent No. 5,965,709 disclose the estimated dosage range to achieve the initial plasma concentration of the antibody for treatment of allergic disease and that U.S. Patent No. 5,783,186 is relied upon to teach the concentration range of administration of antibodies to humans whether iv, sc or im that may be administered in a single bolus injection is about 70 mg in a normal size adult or more in a heavier adult. It is the Examiner's position that US Patent No. 4,093,606 is relied upon for disclosure of a reconstituted (from lyophilized form) formulation of antibody for use in treating a human comprising glycine, albumin and a non-ionic surfactant, the said antibody at high concentration at 50 mg/ml, and that Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and that the antibodies taught by the other references are proteins.

6. Claims 37-39 and 44-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shields et al (Int. Arch. Allergy Immunol. 1995, 107: 308-312) in view of U.S. Patent No. 5,783,186, U.S. Patent No. 5,965,709, U.S. Patent No. 4,093,606 and Cleland et al (Proceed. Intern. Symp. Control. Rel. Bioact. Mater., 22 (1995), pages 514-515).

Shields et al teaches treatment of patients afflicted with IgE-mediated allergy at doses up to 50 mg/kg in monkeys and at 0.5 mg/kg in humans of anti-IgE antibody in single or multidoses, subcutaneously or intravenously.

Shields et al does not disclose the specific concentration of the antibody.

U.S. Patent No. 5,783,186 discloses administration of monoclonal antibodies to humans may be subcutaneous, intravenous or intramuscular and may be a single bolus injection. U.S. Patent No. 5,783,186 further teaches that the amount of antibody to be used will vary depending upon the nature and severity of the condition but in general will range from about 0.1 ug/kg body weight to about 100 mg/kg body weight, i.e., about 70 mg in a normal size adult, more in a heavier adult.

U.S. Patent No. 5,965,709 discloses allergy therapy (i.e., IgE-mediated disease) by administration of an anti-IgE antibody or anti-IgE fragments such as Fab or Fab' (especially col. 32, para 3), including by subcutaneous injection (especially col. 33, para 1) in amounts of about 2-3 mg/kg, i.e., 140 mg to 210 mg in an average adult and including in a single bolus injection (especially column 33, para 4). U.S. Patent No. 5,965,709 further discloses pharmaceutical excipients which would serve as lyoprotectants such as mannitol, lactose, starch, magnesium carbonate, magnesium stearate, sodium saccharin and cellulose (especially col. 33, para 1). U.S. Patent No. 5,965,709 discloses subcutaneous or iv administration (especially column 33 at lines 12-14).

U.S. Patent No. 4,093,606 discloses a reconstituted (from lyophilized form) formulation of antibody for use in treating infection in a mammal, including humans, comprising glycine, albumin and a non-ionic surfactant, the said antibody in the amount of 50 mg/ml (i.e.,5%) (especially column 3 at lines 20-23, column 1 at lines 21-32, column 5 at line 50 through column 6 at line 36).

Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and protein concentrations of 134 mg/ml or 400 mg/ml.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have administered the anti-IgE antibody taught by Shields et al or by U.S. Patent No. 5,965,709 in the amounts disclosed by U.S. Patent No. 5,965,709, U.S. Patent No. 4,093,606 or U.S. Patent No. 5,783,186 in a single bolus as disclosed by

U.S. Patent No. 5,783,186 for administration of monoclonal antibodies to humans at the concentration disclosed by U.S. Patent No. 4,093,606 or higher as taught by Cleland et al for proteins.

One of ordinary skill in the art at the time the invention was made would have been motivated to do this in order to treat allergic diseases as disclosed by Shields et al or by U.S. Patent No. 5,965,709, by routes of administration disclosed by Shields et al or by U.S. Patent No. 5,783,186, in the total amounts disclosed by Shields et al in a single bolus as taught by U.S. Patent No. 5,783,186 or by U.S. Patent No. 5,965,709 at the concentration disclosed by U.S. Patent No. 4,093,606 or higher as taught by Cleland et al for other proteins in order to treat larger size adults or to achieve single bolus injection as disclosed by U. S. Patent No. 5,783,186 in the amounts disclosed by U.S. Patent No. 4,093,606 or U.S. Patent No. 5,965,709.

Applicant's arguments in the amendment filed 4/21/04 have been fully considered but are not persuasive.

Applicant's arguments are of record in the said amendment.

It is the Examiner's position with regard to Applicant's arguments as to Shields et al, that Shields et al teach use of an IgG antibody as does U.S. Patent 5,965, 709. It is the Examiner's further position that U.S. patent No. 5,783,186 and U.S. Patent No. 5,965,709 disclose the estimated dosage range to achieve the initial plasma concentration of the antibody for treatment of allergic disease and that US Patent No. 5,783, 186 is relied upon to teach the concentration range of administration of antibodies to humans whether iv, sc or im that may be administered in a single bolus injection is about 70 mg in a normal size adult or more in a heavier adult. It is the Examiner's position that US Patent No. 4,093,606 is relied upon for disclosure of a reconstituted (from lyophilized form) formulation of antibody for use in treating a human comprising glycine, albumin and a non-ionic surfactant, the said antibody at high concentration at 50 mg/ml, and that Cleland et al teach a method for providing increased stability of proteins using trehalose during lyophilization and that the antibodies taught by the other references are proteins.

7. No claim is allowed.

8. With regard to Applicant's IDS filed 3/30/04, no form 1449 has been received by the USPTO. The references submitted were therefore not considered by the Examiner.

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

10. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Marianne DiBrino whose telephone number is 571-272-0842. The Examiner can normally be reached on Monday, Wednesday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Chan Y Christina, can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Marianne DiBrino, Ph.D.
Patent Examiner
Group 1640
Technology Center 1600
July 30, 2004

CHRISTINA CHAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600